REMARKS

In the Office Action of April 27, 2004, claims 1-23, 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ross, et al. (U.S. Patent No. 5,318,543) in view of Harrison (U.S. Patent No. 5,392,918) and Rudnick et al. (U.S. Patent No. 6,039,183).

Claim 24 was allowed in the Office Action of April 27, 2004.

Applicants respectfully traverse the § 103(a) rejection to claim 1 in view of the combination of Ross, Harrison, and Rudnick. Respectfully, the aforementioned combination of references does not disclose or render obvious a surgical kit that includes a substantially rigid accessory item container configured for holding objects only inside of the container before being opened by a user.

Rudnick discloses a blister package assembly 20 that is configured for holding an aortic arch graph 10. Rudnick provides a blister insert 24 that is positioned on a blister tray 22 (see Rudnick at column 4, lines 4-10). An outer surface of the blister insert 24 has a reverse blister depression 48 formed on one end (see Rudnick at column 3, lines 44-47; and column 4 lines 25-33). A lateral branch 16 of the aortic arch graph 10 is positioned and held in the reverse blister depression 48 in order to space and separate the lateral branch 16 from the aligned branches 14 of the aortic arch graph 10 (see Rudnick at column 4, lines 28-33). Nowhere does Rudnick disclose the holding of objects only inside of the blister insert 24. In fact, Rudnick specifically teaches the exact opposite configuration in providing a reverse blister depression 48 on the outer surface

of the blister insert 24 in order to hold an object thereon. It would not have been obvious for one skilled in the art to modify the blister insert 24 so that the lateral branch 16 is held inside the blister insert 24 because the lateral branch 16 forms a part of aortic arch graph 10 and is in fact integrally formed therewith.

Turning now to Harrison, this reference discloses a sterile packaging that includes a tray and a holder for an intravascular guide-wire. The holder 26 includes an oval raceway 46 that is arranged in order to hold the guide-wire 22E in a compact, coiled condition (see Harrison at column 4, lines 29-35). The guide-wire 22E is retained on both the inside and outside of the holder 26 as shown in Fig. 7. The holder 26 includes an outlet passageway or port 48 through which the distal end of the guide-wire 22E extends (see Harrison at column 4, lines 35-37). The port 48 holds a J-straightener therein so the linearized distal free end of the guide-wire 22E can be readily inserted into an introducer 22B (see Harrison at column 4, lines 47-50). This arrangement of the holder 26 allows the guide-wire 22E to be threaded out of holder 26, and also allows for the guide-wire 22E to be reversed so as to be pushed back through port 48 into raceway 46 and therefore returned into holder 26 (see Harrison at column 4, lines 50-57). Harrison explicitly states that this feature is of "considerable importance" since it reduces the risk of contaminating others with a blood-coated guide-wire (see Harrison at column 4, lines 59-61).

Holder 26 is therefore configured to hold the guide-wire 22E both on the inside and outside of Holder 26. Harrison explicitly teaches that the use of port 48 in holder 26 to hold guide-wire 22E outside of the holder 26 is of "considerable importance" because guide wire 22E is allowed to be re-inserted back into the interior of holder 26. It would

not have been obvious for one skilled in the art to modify holder 26 so that the guide-wire 22E is held only on the inside of holder 26 because doing so would remove a feature of "considerable importance" and would in effect completely frustrate the intended purpose of the holder 26 in Harrison making it impossible to remove and reinsert guide wire 22E.

As such, both Rudnick and Harrison explicitly teach containers that are configured for holding objects on at least the outside of the container. Incorporation of the containers of Harrison and Rudnick into the instrumentation kit of Ross would result in a combined device that has a container configured for holding objects on the outside of the container. To establish *prima facie* obviousness, all of the claim limitations must be taught or suggested by the prior art. Here, a substantially rigid accessory item container that is configured for holding objects only inside of the container before being opened by a user is not taught or suggested by the combination of Harrison, Rudnick, and Ross. Modification of the sealed pouch in Ross upon incorporation of the blister insert 24 of Rudnick and the holder 26 of Harrison would produce a resulting device that includes a container configured for holding objects on the outside of the container. As such, Applicants respectfully submit that claim 1 defines over the combination of Harrison, Rudnick, and Ross and is in condition for allowance. Further, all claims that depend from claim 1 (2-14) are also in condition for allowance. The rejections to claims 2-14 are moot due to the allowability of claim 1.

With respect to claim 15, the Office action of April 27, 2004 states on page 3 that it would have been obvious to one having ordinary skill in the art to modify Ross in view of Rudnick and Harrison as set forth with respect to claim 1, and then further modify this

already modified container so that the container is capable of holding accessory articles as set forth in column 2, lines 40-43 of Ross. Applicants respectfully traverse the § 103(a) rejection to claim 15. There is a lack of motivation for one of ordinary skill in the art to combine and then modify the references as suggested in the Office Action. In fact, there are specific teachings in the references to not modify the references as suggested in the Office Action of April 27, 2004.

Rudnick discloses a blister package 20 that is configured for holding an aortic arch graph 10. The blister insert 24 holds a lateral branch 16 of the aortic arch graph 10 in a reverse blister depression 48 on the outside surface of the blister insert 24 (see Rudnick at column 4, lines 25-33; and Fig. 2). Rudnick does not disclose a container that stores accessory items that include at least a drape, as set forth in claim 15.

The holder 26 of Harrison is specifically designed with top and bottom sections 70, 72 in order to form a raceway 46 into which a guide-wire 22E may be stored, removed, and inserted (see Harrison at column 7, lines 1-3; and column 4 lines 50-61). Harrison does not disclose a container that stores accessory items that include at least a drape. In fact, modifying holder 26 so that it is capable of holding a drape would interfere with the ability of holder 26 to store, dispense, and receive the guide-wire 22E, and as such would completely frustrate the intended purpose of the holder 26 in Harrison.

Ross discloses a drape that is placed loosely in a first recess of tray 13 (see Ross at column 2, lines 38-43). Therefore, the combination of references actually motivate one of ordinary skill of the art to provide for an instrumentation kit in which the surgical drape is placed loosely within the kit as opposed to being stored inside of a

container. Further, Ross is specifically directed towards an instrumentation kit that reduces the amount of packaging of items in the kit (see Ross at column 1, lines 42-45 and 56-59). Ross therefore teaches that it is undesirable to increase the amount of packaging in an instrumentation kit and therefore proposes a solution to this problem by having the drape placed loosely within the kit as opposed to being packaged within the kit. Therefore, the modification or provision of a container that stores a drape goes completely against the combined teachings of Harrison, Rudnick, and Ross.

To establish *prima facie* obviousness, all of the claim limitations must be taught or suggested by the prior art. The Office Action provides no evidence whatsoever for the assertion that it would have been obvious to one having ordinary skill in the art to modify the resulting container obtained upon combining Ross, Rudnick, and Harrison in order to achieve some further modified container that holds a drape. Such a statement is no more than an unsupported conclusion and is not a reason upon which to base a § 103(a) rejection. Applicants respectfully submit that such a series of steps is unobvious to one having ordinary skill in the art and that the percutaneous endoscopic gastrostomy kit of claim 15 could only have been attained by impermissible hindsight upon viewing Applicants' application. There is no motivation for one to combine three references in order to obtain a combined container and then further modify that container in order to achieve a newly modified container capable of holding a surgical drape when the base reference used specifically calls for the drape to be held loosely in the kit, and when the base reference is specifically directed towards a kit that reduces the amount of packaging. Modification in the manner suggested in the Office Action of April 27, 2004 would result in a kit that has increased packaging and as such would go completely

against the teachings and completely frustrate the intended purpose of the base reference.

Therefore, Applicants respectfully submit that claim 15 defines over Rudnick, Ross, and Harrison and the resulting modification of these references and is in condition for allowance. Further, all claims that depend from claim 15 (claim 16-23, 25 and 26) are also in condition for allowance. Their rejections being made moot due to the allowance of claim 15.

Applicants respectfully submit that all claims are allowable and that the application is in condition for allowance. Favorable action thereon is respectfully requested. The Examiner is encouraged to contact the undersigned at the Examiner's convenience should the Examiner have any questions regarding this matter or require any additional information.

Respectfully submitted,

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